

I. ATTACHMENT 8 - 510(K) SUMMARY

K 052874

1. General InformationSubmitter:

MSq. (M²) Ltd.
7 Haeshel Street (P.O.Box 3021)
Caesarea Industrial Park
Caesarea 38900, Israel
Tatiana Epstein
Regulatory Affairs Manager

Contact Person:Summary Preparation Date:

October 23, 2005

2. NamesDevice Names:

SOPRANO™ Hair Removal Diode Laser System

Primary Classification Name:

Surgical Powered Laser Instrument

3. Predicate Device

- MSq MYTHOS™ Hair Removal Diode Laser System (K030805)

4. Product Description

The modified MSq SOPRANO™ Hair Removal Diode Laser System is comprised of the following components:

- Console Unit that includes the main CPU Board, Power Supply Units, Control Panel, Service Panel, Cooling System, Keyswitch, Emergency Stop, and Isolating Transformer;
- Handpiece (with Connector) that includes Optical Head, Tissue Cooling system (the cold plate) and Handpiece Trigger;
- Footswitch.

5. Indications for Use

The SOPRANO™ Hair Removal Diode Laser is intended for hair removal and permanent hair reduction. The SOPRANO™ System is indicated for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

6. Rationale for Substantial Equivalence

The modified MSq SOPRANO™ Hair Removal Diode Laser System shares the same indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate MSq MYTHOS™ Hair Removal Diode Laser System (K030805).

7. Safety and Effectiveness Information

The review of the indications for use, technical characteristics, risk analyses, and verification and validation information provided demonstrate that the modified MSq SOPRANO™ Hair Removal Diode Laser System is substantially equivalent to the predicate device.

8. Conclusion

The modified MSq SOPRANO™ Hair Removal Diode Laser System was found to be substantially equivalent to the predicate MSq MYTHOS™ Hair Removal Diode Laser System (K030805).

The modified MSq SOPRANO™ Hair Removal Diode Laser System shares identical indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 22 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tatiana Epstein
Regulatory Affairs Manager
MSq. (M²) Ltd.
7 Haeshel Street (P.O. Box 3021)
Caesarea Industrial Park
Caesarea 38900, Israel

Re: K052874

Trade/Device Name: SOPRANO™ Hair Removal Diode Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic
surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 26, 2005
Received: October 28, 2005

Dear Ms. Epstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Barbara Buehner" with a stylized flourish at the end.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. ATTACHMENT 2 - INDICATIONS FOR USE STATEMENT AS REQUESTED BY FDA

**510(k)
Number
(if known)**

K 052874

Device Name SOPRANO™ Hair Removal Diode Laser System

**Indications
for Use**

The SOPRANO™ Hair Removal Diode Laser is intended for hair removal and permanent hair reduction.
The SOPRANO™ System is indicated for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**